REMARKS

Status of the Claims

Claims 1, 2, 4-27, and 52-53 are pending in the present application, Claims 28-51 (corresponding to non-elected claims) having been canceled without prejudice in response to a restriction requirement, subject to applicants' right to file a divisional patent application directed to such claims, Claim 3 having been otherwise cancelled, Claims 52 and 53 having been added, and Claims 1, 2, 4-7, 12, 21-24, and 27 having been amended to more clearly define the invention.

Claim 4 Rejected Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected Claim 4 since the recited term "a scalp portion" lacks antecedent basis, because reference to a scalp portion on the model does not exist in the parent claim.

Applicants respectfully submit that Claim 4 does not recite the term "a scalp portion." It appears that the Examiner instead meant to reject Claim 6, which does recite the term. However, applicants have amended Claim 6 to recite that the model comprises a scalp portion, thereby obviating the antecedent basis issue in regard to this claim. Accordingly, applicants respectfully request that the Examiner withdraw this rejection.

Claim 15 Rejected Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected Claim 15 as failing to comply with the enablement requirement, because the claim contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, Claim 15 discloses two materials, a first and third material, which are substantially similar in echogenicity. The Examiner notes that the third material is specifically disclosed in the specification and claimed as dimethyl siloxane, hydroxy-terminated polymers, and silica (also known as SILLY PUTTY™). The Examiner then asserts that the disclosure fails to provide materials that are substantially similar to the ***third*** material. Since the Examiner has already admitted that the specification and claims recite the nature of the third material, it appears that the Examiner meant to assert that the specification fails to disclose what material can be used to implement the ***first*** material.

If so, applicants respectfully disagree, because the disclosure provides details relating to how both the first and third materials can be implemented. As noted by the Examiner, the third material can be implemented using dimethyl siloxane, hydroxy-terminated polymers, and silica (also known

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as SILLY PUTTY™). The specification quite clearly describes the first material as being a plastic/polymer. The disclosure recites:

> An empirical model was constructed using a doll's head ***made from a plastic material***. Openings representing patent skull sutures were formed in the doll's head at anatomically correct positions. The openings were filled with a children's play product marketed under the name GOOOZE™. In ultrasound images of the doll's head, the simulated patent skull sutures filled with GOOOZE™ were easily identifiable. Indeed, as will be discussed in detail below, the ultrasound images of the doll's head were remarkably similar to ultrasound images of human patients. While GOOOZE™ is a proprietary formula, a similar patent skull suture fill material can be produced using a mixture of starch and glue. The glue can be either a casein-based glue or a synthetic resin-based glue. (Specification, page 10, lines 3-12, emphasis added; also, note that the glue-based material is a second material, which is both described in the specification and claimed.)
>
> The above discussion assumes that most of the model is produced from the same material ***(i.e., a plastic used to make a doll's head)***. It should be noted that the model is intended to be used for craniosynotosis screening. As such, the portion of the model that will be ultrasonically scanned is the skull portion. Thus, the above references to the material of the model are particularly intended to refer to the skull portion of the model. While it likely will be more expensive to produce a model in which the skull portion is fabricated of a different material than the facial portion of the model, such a model is possible, and it should be understood that the above discussion as to preferred model materials is directed to the skull portion of the model that is ultrasonically imaged during craniosynotosis screening. Thus, models that use one material for the skull portion, and one or more other materials for the facial or other portion of the model, are encompassed by the present invention. (Specification, page 12, lines 19-31, emphasis added.)
>
> It should be understood that the actual material selected as a patent skull suture fill material is less critical than ensuring that the patent skull suture fill material has a different echogenicity than that of the model. While the use of an existing doll's head made the preparation of an empirical model simple, it should be understood that rather than using an existing doll's head, a specially built model could be fabricated. ***If specifically fabricated as a craniosynotosis screening model, the fabricator can control the selection of the material used for the model, as well as the selection of the material used for the patent skull suture fill. Thus, a fabricator can ensure that each material is easily distinguished from the other in an ultrasound image. Many different types of materials can be used to produce models, including wood, plaster, ceramics, and polymers. Polymers are likely to be a particularly preferred material for this application, because injection molding techniques can be used to produce large numbers of models at a reasonable cost***. (Specification, final paragraph on page 10, emphasis added. Note that this section discloses that the first and third material can be fabricated from many types of materials, including polymers, so long

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as care is taken to ensure the materials used for the first and third materials have similar echogenicities.)

As will be evident from the above quoted portions, the specification clearly discloses the nature of the materials that can be used to implement the recited first and third materials, thus, applicants respectfully request that the Examiner withdraw his rejection of Claim 15.

Claims Rejected Under 35 U.S.C. § 102(a)

The Examiner has rejected Claims 1-5, and 20-24 under 35 U.S.C. § 102(a) as being anticipated by an Internet-based document relating to an infant skull model, labeled "Infant Skull Model and Sculpted Head" (retrieved on Jun 09, 2002), herein referred to as NPL #1. The Examiner notes that NPL #1 discloses a skull model with visibly anatomically correct patent sutures. The Examiner asserts that because the skull model is made of a first material, and that the patent sutures (which are depressions formed into the model) are filled with air (a second material), the patent sutures would be visible in an ultrasound image of the model.

Applicants respectfully disagree with the Examiner's conclusion that the air-filled patent sutures in the infant skull model will be visible in an ultrasound image of the skull model. This issue is addressed below, in connection with the section titled *Patentability of Newly Added Claims*. Even though applicants disagree with the Examiner's rejection, in the interests of advancing prosecution of the present application, independent Claims 1, 21, and 27 have been amended to more clearly distinguish over the cited art, as discussed in detail below.

The Scope of NPL #1

NPL #1 is a picture that includes a sculpture of the head of an infant (the sculpted head in the left portion of the picture) and a model of the skull of an infant (the skull model in the right portion of the picture). The *skull model* clearly includes patent skull sutures. There is no basis to conclude that the *sculpted head* includes any simulated skull sutures, patent or fused. Applicants' claims consistently recite a life-size model of a *human head*, not a life-size model of a *human skull*. There appears to be no basis to conclude that an artisan of ordinary skill in the medical arts would have considered a head to be equivalent to a skull, just as an artisan of ordinary skill in the medical arts would not consider a medical mannequin to be equivalent to a model of the human skeletal system.

With respect to the rejection of applicants' claims as being anticipated, in addition to the reasons noted in traversing this rejection as set forth in detail below, it should be recognized that

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NPL #1 cannot anticipate the claimed invention, because NPL #1 does not disclose a life-size model of a human head that includes a patent skull suture. The model of an infant ***skull*** provided by NPL #1 is clearly not equivalent to a life-sized model of a human ***head***.

With respect to the obviousness rejections, in addition to the traverse of the obviousness rejections discussed in detail below, it should be recognized that NPL #1 does not teach or suggest that the simulated skull sutures in the skull model should be incorporated into a sculpted head. Thus, the cited art does not teach or suggest a life-size model of a human head that includes a simulated patent skull suture. Nor is there any evidence that the artisan of ordinary skill in the art would recognize that a model of a human skull is equivalent to a model of a human head, such that a skull model might be substituted for a model of a human head. These two types of models are structurally distinguishable, and are generally used for entirely different purposes.

Patentability of Independent Claim 1

With respect to NPL #1, the Examiner has concluded that air and the material from which the skull model has been formed have different echogenicities, such that the air filled sutures (depressions) would be distinguishable from the material forming the model. Applicants have amended the claims, which as amended, distinguish over the cited art for the following reasons.

Claim 1 as amended recites:

> A medical simulator for training ultrasound operators to perform craniosynotosis screenings using medical ultrasound, comprising a substantially life size model of a human head, said model being at least in part fabricated from a first material, said model including at least one simulated patent skull suture being at least in part fabricated from a second material, said second material comprising at least one of a solid and a semi-solid, an echogenicity of said second material being substantially different than an echogenicity of said first material, such that each simulated patent skull suture can be readily distinguished in an ultrasound image of said model.

The Examiner has rejected Claim 1 because NPL #1 discloses a skull model that includes a patent skull suture formed by depressions in the skull model. The Examiner asserts that these depressions will be filled with ambient air, and in an ultrasound image, the ambient air in those depressions would be distinguishable from the balance of the skull model, enabling the patent sutures to be identified in the ultrasound image.

As amended, Claim 1 recites a model of a human head that is fabricated from a least a first material and a second material. The second material, either a solid or semi-solid, is used to fabricate

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at least a portion of the simulated patent sutures. NPL #1 provides absolutely no evidence to enable one to reasonably conclude that the skull model of NPL #1 is fabricated for more than one type of material, or that at least a portion of the simulated patent sutures are fabricated from a different material. While the Examiner is correct that the depressions corresponding to the simulated patent sutures are filled with ambient air, it is illogical to conclude that ambient air is equivalent to a solid or semi-solid material that is used in the fabrication of a model. The ambient air plays no role in the manufacture or fabrication of the model, but instead, simply occupies a void in the material from which the model of the infant skull is fabricated.

Clearly, NPL #1 cannot anticipate Claim 1 as amended, because the ambient air filling the depressions corresponding to the simulated patent sutures is not a solid or semi-solid material, as now recited in Claim 1.

With respect to obviousness, the Examiner has previously argued that an artisan of ordinary skill in the art would have recognized that the ambient air filling the depressions corresponding to the simulated patent sutures in the skull model could be replaced by a mixture of starch and glue, because the artisan of ordinary skill would recognize that ambient air and a starch/glue mixture are equivalent. The Examiner further asserts that both the ambient air and the start/glue mixture are less echogenic than solid portions of the simulated skull. For the following reasons, this position seems unjustified. First, it must be recognized that a gas is not the structural equivalent of a solid or semi-solid, particularly in regard to the reflectivity of ultrasound used for imaging. Second, it must be recognized that as amended Claim 1 recites that the second material is used to *fabricate* a model (i.e., it is physically incorporated into and employed in creating the model, as opposed to simply being part of the environment around the model). Accordingly, it will be evident that ambient air is not used to fabricate the skull model of NPL #1.

Thirdly, and most importantly, NPL #1 simply does not teach or suggest that the skull model be used for creating ultrasound images. Indeed, the web site of the artisan, Linda Webb, who developed the sculpted head shown in NPL #1, specifically disclosed that the use of the infant skull model enables her to generate realistic and anatomically correct sculptures of infant heads (see lindawebb.com/aboutlinda.htm). In other words, NPL #1 and its related context indicates only that the infant skull model can be used to generate a realistic looking sculpture of an infant's head. NPL #1 clearly does not teach that the simulated patent skull sutures could be identified in ultrasound

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images of the skull model because the ambient air filling the depressions corresponding to the simulated skull sutures has a different echogenicity than the material from which the skull model is fabricated. Accordingly, there is not justification for the Examiner to argue that the substitution of a material also having a different echogenicity than the material from which the skull model is fabricated, to fill the voids, might simply be a matter of design. However, the record simply does not support a conclusion that a design criteria in developing the skull model of NPL #1 was motivated by selecting a fill material for enabling the simulated patent skull sutures to be distinguished in an ultrasound image. NPL #1 does not even teach or suggest that the depressions corresponding to the simulated patent sutures should be filled with *any* material at all. The Examiner's position thus corresponds to an improper application of hindsight, rather than being a well-founded obviousness rejection.

Finally, note that Claim 1 specifically recites that the echogenicities of the first material and the second material are substantially different. The Examiner has previously asserted that the echogenicity of air is lower than the solid portion of the skull model, however, NPL #1 does not provide any teaching or details comparing the echogenicity of air with that of the material from which the model is made. Applicants, who are experts in ultrasound imaging, particularly dispute the Examiner's assertion that air is hypoechoic, and thus, could be expected to have a lower echogenicity than some arbitrary type of material comprising a solid portion of the skull model. In the context of medical ultrasound, it is well recognized that air dramatically attenuates ultrasound waves, and when an air layer is disposed next to a boundary of solid material or semi-solid material, the large difference in the density of air and the other material will cause a substantial reflection of the ultrasound waves. That is why medical ultrasound employs coupling gels or fluid-filled balloons between an ultrasound probe and the tissue of a patient, to provide good coupling between the ultrasound probe and the tissue mass. The gel or liquid-filled balloon avoids an air layer being disposed between the ultrasound probe and a tissue mass. With reference to the air-filled depressions in the infant skull model, if an ultrasound image of the skull model was obtained and a coupling gel or fluid-filled balloon were used to displace the air filling the depressions, there would be no second material having a different echogenicity that could be observed in the ultrasound image. If no coupling gel or fluid-filled balloon were used to displace the air filling the depressions corresponding to the simulated skull sutures, then the large density difference between the air filling the depression

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and the solid portion of the model at the bottom of the depressions corresponding to the simulated patent skull sutures would result in a *VERY* strong reflection of ultrasound energy. Such a strong reflection of ultrasound is simply not a characteristic of a *hypoechoic* material; instead, it is a characteristic of a *hyperechoic* material. If the Examiner were correct in asserting that the solid portion of the skull model is made of a highly echogenic material (noting that the record provides absolutely no evidence as to the actual echogenicity of the material from which the skull model is made), then in an ultrasound image of the skull model, both the solid portion of the skull model and that the air-filled depressions corresponding to the simulated patent skull sutures would reflect ultrasound very strongly, and it would therefore be difficult to distinguish the simulated patent skull sutures in the ultrasound image, since the simulated patent sutures and the portion of the model adjacent to the simulated patent sutures will both appear bright in an ultrasound image.

Applicants respectfully submit that the air-filled patent sutures in NPL #1 will show up as bright spots in an ultrasound image of the skull model shown in NPL #1 (because air is hyperechoic in medical ultrasound). If necessary, applicants can submit a declaration to the effect that air is hyperechoic in the context of medical ultrasound. However, the fact that air is hyperechoic is notoriously well known in the medical ultrasound arts, and such a declaration should not be necessary to establish this well-known and accepted characteristic.

To achieve an equivalent structure, the patent sutures in the skull model of NPL #1 would have to be filled with or fabricated of a solid or semi-solid material having a distinguishably different echogenicity than the material from which the balance of the model is formed. The cited art simply does not teach or suggest such a modification of the skull model shown. Accordingly, Claim 1 and each claim dependent thereon patentably distinguish over the cited art, and the rejection of Claims 1, 2, 4, and 5 under 35 U.S.C. § 102(a) should be withdrawn (Claim 3 having been canceled).

Patentability of Dependent Claim 4

Significant differences exist between Claim 4 and the cited art because the cited art does not teach or suggest that a second material used in a model of a head is *hypoechoic*. The Examiner has asserted that the depressions forming the patent sutures in NPL #1 are filled with air, and has concluded that air is a hypoechoic material. Applicants respectfully submit that one of ordinary skill in the medical ultrasound arts would definitely not consider air to be a hypoechoic material (i.e., a material that does NOT strongly reflect ultrasound waves). Indeed, air and other gases are regularly

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used as examples of hyperechoic materials (i.e., materials that DO strongly reflect ultrasound waves). (Indeed, gas-filled microbubbles are used as ultrasound contrast agents for this reason.) Should the Examiner continue to maintain that air is a hypoechoic material, applicants respectfully request that the Examiner enter into the record some reference that supports that assertion. It is applicants' position that Claim 4 distinguishes over the cited art for this additional reason.

Patentability of Dependent Claim 5

Significant differences exist between Claim 5 and the cited art, because the cited art does not teach or suggest that in an ultrasound image of the model, portions of the model corresponding to a first material appear as relatively bright portions in an ultrasound image, and portions of the model corresponding to a second material appear as relatively dark portions in an ultrasound image. As discussed above in detail with respect to the rejection of Claim 4, air is a hyperechoic material that will result in strong reflections, which will appear as bright portions in ultrasound image. Claim 5 distinguishes over the cited art for this additional reason.

Patentability of Dependent Claim 20

NPL #1 clearly illustrates an infant skull model and a sculpted head. Claim 20 specifically recites using a doll's head for the model of a human head. Clearly, a skull model (which includes patent sutures) ***is not*** equivalent to a doll's head. The Examiner may assert that the sculpted head of NPL #1 could be considered to be equivalent to a very detailed doll's head. However, there is simply no evidence that the sculpted head of NPL #1 (i.e., the leftmost portion of the image) includes the patent sutures in the skull model (i.e., the rightmost portion of the image). NPL #1 cannot anticipate Claim 20, because the sculpted head does not include patent sutures, and the skull model is not equivalent to a doll's head. The prior art does not teach or suggest that the patent sutures in the skull model should be incorporated into the sculpted head. Claim 20 therefore patentably distinguishes over the cited art for this additional reason.

Patentability of Independent Claim 21

Applicants have amended Claim 21 to recite a model including at least one opening corresponding to a patent skull suture, in which the opening is filled with a ***solid or semi-solid*** hypoechoic material, thereby enabling the patent skull suture to be distinguishable in an ultrasound image of the model.

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Regardless of the echogenicity of the air filling the patent sutures in NPL #1, air most definitely is not a solid or a semi-solid. The cited art does not teach or suggest filling the depressions corresponding to the patent sutures in the skull model of NPL #1 with a solid or semi-solid hypoechoic material. Gases *ARE NOT* equivalent to solids/semi-solids. Thus, there is absolutely no reason an artisan of ordinary skill in the art would have been led to replace the air filling the opening with a solid or semi-solid.

Accordingly, the rejection of independent Claim 21 under 35 U.S.C. § 102(a) should be withdrawn. Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claims 22-24 are patentable for at least the reasons discussed above in regard to independent Claim 21, and the rejection of dependent Claims 22-24 under 35 U.S.C. § 102(a) should also be withdrawn.

Patentability of Dependent Claims 22 and Claim 24

Claim 22 as amended recites that "*when the medical simulator is imaged using ultrasound, the hypoechoic material produces a relatively dark image, whereas adjacent portions of the model produce a relatively bright image, such that each simulated patent skull suture appears in the ultrasound image as a relatively dark area surrounded by relatively brighter areas.*" The cited art does not teach or suggest a model that includes a patent skull suture, which when imaged using medical ultrasound, appears in the ultrasound image as a relatively dark portion surrounded by relatively bright portions. While the echogenicity of the material used to form the skull model of NPL #1 is not actually known, it is likely that the material, which is simulating bone, will be a relatively good reflector of ultrasound, and therefore will appear in ultrasound image as a relatively bright skull shaped object. As noted above, applicants believe that an artisan of ordinary skill in the art would recognize that air is a hyperechoic material, and the air in the patent sutures will show up in an ultrasound image as a bright spot. Thus, the patent skull sutures in the skull model of NPL #1 will likely show up in an ultrasound image as relatively bright areas surrounded by other relatively bright areas. Claim 22 patentably distinguishes over the cited art for this additional reason.

Claim 24 has been similarly amended, and patentably distinguishes over the cited art for substantially the same reasons as Claim 22.

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Patentability of Dependent Claim 23

Claim 23 specifically recites a model that is formed out of a first material and openings in the model corresponding to patent sutures are filled with a second material, and that the second material has a substantially different echogenicity than the first material. The Examiner has argued that air has a substantially different echogenicity than the material from which the skull model in NPL #1 is formed. Applicants respectfully submit that the cited art provides absolutely no evidence as to what the echogenicity of ***either*** air or the material from which the model is made; thus, no reasonable conclusion can be drawn as to whether the echogenicity of these two materials are substantially different or the same. Accordingly, NPL #1 cannot teach or suggest the recitation of Claim 23 and cannot be a basis for rejecting Claim 23. Claim 23 thus patentably distinguishes over the cited art for this additional reason.

Claims Rejected Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 7-9, 10-11 under 35 U.S.C. § 103(a) as being unpatentable over Infant Skull Model (NPL #1). The Examiner has also rejected Claims 12-14, 25 and 27 as being unpatentable over NPL #1 and further in view of Chelue's Fabrication of Medical Model from scan data via rapid prototyping (hereinafter referred to as "NPL #2"). The Examiner has rejected Claim 18 as being unpatentable over NPL #1 in view of NPL #2 and further in view of U.S. Patent No. 4,773,865 (hereinafter referred to as "Baldwin"). Claim 19 is rejected as being unpatentable over NPL #1 and further in view of Baldwin.

Patentability of Dependent Claims 7-9

Significant differences exist between Claims 7-9 and the cited art because the Examiner has not established a *prima facie* case of obviousness, since there is NO suggestion or motivation in the knowledge generally available to one of ordinary skill in the art to modify the reference cited, as proposed by the Examiner. A portion of dependent Claim 7 recites "…wherein the second material comprises a mixture of a starch and a glue;" a portion of dependent Claim 8 recites "wherein the glue is a casein-based glue;" and, dependent Claim 9 recites "…wherein the glue is a synthetic resin-based glue." The Examiner asserts that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model the sutures using air or starch and glue mixtures. Furthermore, the Examiner asserts that one of ordinary skill in the art would have expected both solutions to work equally well, since the echogenicity of both materials are less than

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the solid portion of the skull. The Examiner concludes that it would have been *prima facie* obvious to modify NPL #1 to obtain the invention as specified in Claims 7-9, because such a modification would have been considered a mere design consideration, which fails to patentably distinguish over the prior art of NPL #1.

Applicants respectfully disagree. The argument that the substitution of an element disclosed in the prior art with a recited element is simply a matter of design is only logical where there is a clear indication that the artisan of ordinary skill in the relevant art would recognize that the substituted elements are equivalent. For example, where a reference discloses the use of a particular steel alloy, and the claimed invention recites the use of a different steel alloy, and there is evidence that an artisan of ordinary skill would recognize that each alloy could be used interchangeably (i.e., the alloys didn't have materially different properties which would provide some additional functionality if one alloy were substituted for the other), it can logically be argued that choice of which particular alloy to use would simply be a matter of design well within the scope of the skill of the artisan. However, in context of the instant application, the Examiner appears to be arguing that an artisan of ordinary skill in the skull model arts would recognize that air and glue mixtures are functionally equivalent, and the artisan of ordinary skill in the art would have been readily motivated to substitute one element to the other, even though there is no teaching or suggestion in the cited references of using the skull model for ultrasound imaging. Such a conclusion does not appear to be well reasoned.

The patent sutures in the skull model of NPL #1 are not filled with anything when the model is being made. Ambient air simply fills the depressions representing the patent sutures. The cited art provides no evidence as to why an artisan of ordinary skill in the art would have been led to understand that any benefit could be obtained by filling the patent sutures with some material other than ambient air. Note that the artisan of NPL #1 never chose to fill the patent sutures with anything (and as a result, the air is simply present in the void). Thus, it is illogical to assert that it would have been obvious to such an artisan to select a material for filling the patent sutures, *other* than air. Filling the patent sutures with some different material (i.e., a material other than ambient air) would lead to an increase in complexity and cost for producing the model, and the Examiner has not provided any evidence that the artisan of ordinary skill in the art would recognize any benefit for incurring this additional complexity/expense, since the model skull is not intended to be used for

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ultrasound imaging. Furthermore, there is absolutely no evidence that the artisan of ordinary skill in ultrasound arts would recognize that air and starch/glue mixtures are functionally equivalent. No evidence has been submitted that air and starch/glue mixtures respond identically to ultrasound (indeed, applicants have traversed the Examiner's assertion that air is hypoechoic). Applicants' disclosure clearly indicates that starch/glue mixtures are hypoechoic, such that when imaged using ultrasound they appear as dark areas in the ultrasound image. Significantly, air is a gas, and starch/glue mixtures are semi-solids or solids, and the two have very different structural and other properties. Thus, they are not equivalent, and it is unreasonable to assert that an artisan of ordinary skill in ultrasound arts would have viewed them as equivalents.

Furthermore, a review of the source of NPL #1 (see lindawebb.com/aboutlinda.htm) reveals a web site of an individual, Linda Webb, who creates life-like sculptures of infants. In addition, a caption under NPL #1 on the web site explains that "Linda uses this skull model to help her achieve the proper head shape of an infant." Thus, she looks at the skull model when shaping a sculpture of an infant; indeed, her web site explains that she specializes in realistic, newborn sculptures. Thus, she is an artist making realistic sculptures of babies. So one of ordinary skill in the art of NPL #1 would be an artisan who studies human anatomy in order to recreate life-like sculptures. There is absolutely no evidence that the models disclosed in NPL #1 were ever designed for or intended to be used for ultrasound imaging, and such an artisan would not be selecting a fill material based on echogenic properties of the fill material. Instead, the emphasis of NPL #1 is clearly based on viewing the model with the human eye, not imaging the model with medical ultrasound.

Accordingly, because the cited art does not teach or suggest the recitation of dependent Claims 7-9, the rejection of dependent Claims 7-9 under 35 U.S.C. § 103(a) should be withdrawn. In addition, the rejection should be withdrawn because these claims depend from independent Claim 1 which is patentable for the reasons described above.

Patentability of Dependent Claims 10-11

Claims 10-11 patentably distinguish over the cited art for substantially the same reasons as independent Claim 1, whose patentability has been discussed in detail above.

Patentability of Dependent Claim 26

Claim 26 patentably distinguish over the cited art for substantially the same reasons as independent Claim 21, whose patentability has been discussed in detail above.

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Patentability of Dependent Claims 12 and 13

Claims 12 and 13 patentably distinguish over the cited art for substantially the same reasons as independent Claim 1, whose patentability has been discussed in detail above.

Patentability of Independent Claim 27

Claim 27 as amended recites a model of a human head including both fused and patent skull sutures, that is configured such that in an ultrasound image of the model, *each simulated patent skull suture will appear dark in such an ultrasound image, and each simulated fused skull suture will appear bright in such an ultrasound image.* As discussed in detail above, NPL #1 does not specify the material from which the skull model including the patent sutures is formed, and it cannot be ascertained with certainty whether the skull model would appear bright or dark in ultrasound image. Even more significantly, because air and other gases are hyperechoic to medical ultrasound (particularly the boundary layer between air and a solid or semi-solid material, such as at the bottom of the depressions corresponding to the simulated patent skull sutures of NPL #1), the air-filled patent sutures of NPL #1 will logically appear as bright spots in the ultrasound image. Because of this, the patent sutures will either appear as bright areas surrounded by other bright areas (if the material from which the skull model is fabricated is hyperechoic), or as bright areas surrounded by dark areas (if the material from which the skull model is fabricated is hypoechoic). Neither configuration is equivalent to that claimed by applicants, nor is there any evidence that it would have been obvious to an artisan of ordinary skill in the ultrasound arts to modify the skull model disclosed by NPL #1 to achieve the dark patent sutures/bright bone ultrasound image recited in Claim 27.

Accordingly, because the cited art does not teach or suggest the recitation of independent Claim 27, the rejection of independent Claim 27 under 35 U.S.C. § 103(a) should be withdrawn.

Patentability of Dependent Claim 14

Claim 14 recites a model in which fused skull sutures comprise openings in a first material that has been filled with a third material that has an echogenicity substantially similar to the first material. NPL #1 discloses a skull model including patent skull sutures filled with air. NPL #2 discloses fabricating a medical model based on medical images, with one such model being a model of a human head that includes a fused skull suture. The Examiner asserts that the fused skull suture in NPL #2 must reasonably be formed out of the same material as the rest of the model of the head.

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It must be recognized that the structure recited in Claim 14 is a model of the human head formed out of the first material, and openings are made in that first material. Then, those openings are filled with either a second material (for patent sutures), or a third material (for fused sutures). In contrast, NPL #2 discloses making medical models using rapid prototyping. Rapid prototyping employs either an additive or subtractive process. In the additive process, layers of material are built up over time until the desired three-dimensional shape is achieved. In the subtractive process, a mass of material is initially provided, and material is selectively removed until the desired three-dimensional shape is achieved. Neither of these processes would result in a structure in which an opening is formed in a first material ***and then filled with a third material***. In the additive process, the opening would never be formed because the fused skull suture would be formed as a solid portion of the model. In the subtractive process, the opening would never be formed because the prior art does not teach or suggest why it would be useful to form an opening and fill it with an additional material. This is not simply a matter of design, the prior art simply does not recognize any utility to forming an opening and then filling it with a material that cannot be distinguished from the first material in ultrasound image. Applicants' disclosure clearly indicates that it would be useful to form openings corresponding to each skull suture, and selectively fill some of those openings with the third material, to be able to determine if an ultrasound technician can differentiate a fused skull suture from a patent skull suture.

Significantly, the Examiner has asserted that it would have been obvious to an artisan of ordinary skill in the ultrasound arts to fill openings/depressions corresponding to patent skull sutures with a third material so that those openings would appear to correspond to a fused skull suture in an ultrasound image. However, this assertion is unsupported by any of the prior art. The Examiner has cited no reference indicating that an artisan of ordinary skill would have recognized that an opening corresponding to a patent skull suture could be made to appear as a fused skull suture in ultrasound image by selectively filling that opening with a material having an appropriate echogenicity. Note NPL #2 is not about imagining a model using ultrasound, it is about making a model based on ultrasound images of a patient.

Absent any teaching in the prior art, such a rejection is based on hindsight, and hindsight clearly cannot form the basis of a valid obviousness rejection. Claim 14 is patently distinguishable

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over the cited art because prior art does not teach or suggest the modifications required to achieve an equivalent structure, and its rejection should therefore be withdrawn.

Patentability of Dependent Claim 25

Claim 25 patentably distinguishes over the cited art for substantially the same reasons as dependent Claim 14 and independent Claim 21, the patentability of each having been discussed in detail above.

Patentability of Dependent Claims 15-17

Claims 15-17 patentably distinguish over the cited art for substantially the same reasons as dependent Claim 14.

Patentability of Dependent Claims 18 and 19

Claims 18 and 19 recite including an opaque layer over portions of the model, to prevent a user of the model from visually identifying patent versus fused skull sutures. The Examiner asserts that it would have been obvious to add the simulated skin disclosed by Baldwin to the skull model disclosed by NPL #1, *in order to simulate a tactile feature of a human infant*. This motivation appears to be poorly reasoned. A skull model serves the purpose of enabling normally hidden structures to be readily observable – and in the present instance, the cited skull model is intended to be viewed while sculpting a life-like head of an infant. If it would have been desirable to have a tactilely accurate model of the head of an infant, then logically, the sculpted head of NPL #1 would have been formed using tactilely correct materials. It does not appear logical to cover the skull model with skin in order to achieve a tactilely correct representation, particularly because ***skeletal*** models are not intended to be used to tactilely represent skin. Even more significantly, the opaque layer recited by applicants is not functionally equivalent to the skin layer disclosed by Baldwin. The skin layer disclosed by the prior art serves the function of enabling a student to simulate the tactile sensation of the human body. The opaque layer recited by applicant simply prevents the user from visually identifying the difference between a patent or fused skull suture. The prior art simply does not teach or suggest adding an opaque layer of material to a medical model of a human head that includes both simulated patent skull sutures and simulated fused skull sutures, in order to prevent a user from ***visually*** differentiating the fused skull sutures from the patent skull sutures.

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Patentability of Dependent Claim 6

Applicants do not see where the Examiner has cited a reference with respect to dependent Claim 6. Nevertheless, because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claim 6 is patentable for at least the reasons discussed above in regard to independent Claim 1 from which it depends. Furthermore, Claim 6 has been amended to recite that the second material is used to cover the scalp portion, even beyond the openings in the first material, to prevent a user from tactilely determining the locations of the simulated patent skull sutures, as fully disclosed in the specification as filed.

Patentability of Newly Added Claims

Newly added Claim 52 recites a model including a nose, two ears, two eyes, a mouth, and at least one simulated patent skull suture whose echogenicity enables the simulated patent skull suture to be identifiable in an ultrasound image of the model. Significantly, NPL #1 discloses a sculpted infant head that includes realistic and lifelike features such as eyes, a nose, a mouth and ears. NPL #1 also discloses an infant skull model including simulated patent sutures. The Examiner further asserts that the skull sutures can be readily identified in an ultrasound image. Even if the Examiner is correct that the skull sutures in the infant skull model can be identified using medical ultrasound, NPL #1 does not teach or suggest obtaining medical ultrasound images of either the sculpted head or the skull model, nor that there would be any benefit to incorporating the realistic lifelike features of the sculpted head into the skull model, or incorporating the simulated patent sutures of the skull model into the sculpted head. Accordingly, Claim 52 patentably distinguishes over the cited art.

Claim 53 recites a model including at least one simulated patent skull suture, an echogenicity of each simulated patent skull suture enabling the simulated patent skull suture to be readily distinguishable in an ultrasound image of said model, such that each simulated patent skull suture will appear dark in such an ultrasound image, whereas adjacent portions of said model will appear bright in such an ultrasound image. The Examiner has previously asserted that ambient air in the depressions corresponding to simulated patent skull sutures in the skull model of NPL #1 will be distinguishable in an ultrasound image of the skull model, because air has a lower echogenicity than the material from which the skull model is fabricated. *Arguendo*, if the Examiner were correct, then the simulated patent skull sutures would appear dark in the ultrasound image. However, applicants respectfully submit that the interaction between medical ultrasound waves and air would result in the

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simulated patent skull sutures in the skull model of NPL #1 appearing as bright spots in an ultrasound image, not dark spots.

Applicants respectfully request the Examiner consider the following.

Air gaps represent a unique phenomena in ultrasound imaging, and the effect of an air gap on ultrasound imaging merits discussion. Artisans of ordinary skill in the art of ultrasound imaging will readily recognize that air attenuates ultrasound transmission by orders of magnitude more than do most solid or liquid materials. Thus, attempting to image an object using ultrasound transmitted across an air gap is generally undesirable. Furthermore, ultrasound waves are reflected at the boundary between materials having different densities. Thus, where an air gap exists between an imaging transducer (or probe) and a solid or liquid material, a significant amount of the ultrasound wave energy will be reflected back to the transducer at that air gap boundary, making imaging of any underlying structures very difficult. In the context of medical ultrasound imaging, ultrasound coupling gels are used to eliminate an air gap/layer between an ultrasound probe and a tissue layer, because the air layer will not only attenuate the ultrasound waves, but will also cause significant reflections.

Because of this phenomenon, in the ultrasound arts, it is well recognized that air is a hyperechoic material. The ability of air (or gases in general) to strongly reflect ultrasound waves has several different impacts on ultrasound applications. In addition to the use of coupling gels or fluid filled balloons discussed above, air and other gases are also used as ultrasound contrast agents because of their high echogenicity. For example, microbubbles (air or gas filled spheres) are used as ultrasound contrast agents, because when microbubbles are introduced into the body, such as the vascular system, such microbubbles are extremely visible in an ultrasound image, enabling vascular systems to be mapped with great accuracy.

The response of ultrasound to a boundary layer between air and a solid or semi-solid material is particularly significant. As noted above, where there is a large difference in density between the materials at this boundary, very large reflections will occur. Because of this characteristic, it is very difficult to obtain ultrasound images beyond an air/solid boundary (which is why coupling gels or fluid-filled balloons are employed in the context of medical ultrasound; to eliminate an air/tissue boundary layer, the density of the coupling gel or fluid-filled balloon being much closer to the density of tissue). With respect to NPL #1, the boundary layer between the ambient air filling the

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depressions corresponding to the simulated patent skull sutures and the solid material from which the skull model is fabricated will result in very strong reflections; thus, the simulated patent skull sutures will appear as bright portions in an ultrasound image of the skull model. Claim 53 specifically recites that the simulated patent suture appears as a dark spot in ultrasound image. Applicants ensure that this result is achieved by using a hypoechoic material to simulate the patent skull sutures. Note Claim 53 recites an opposite of the imaging phenomenon that will logically occur when the skull model of NPL #1 is imaged using ultrasound (i.e., the patent sutures will appear as bright spots in an ultrasound image due to the strong reflection at the air/solid boundary at the bottom of the depressions). This result is the opposite of what applicants recite in the claim. The cited art does not teach or suggest how the opposite result can be achieved. Accordingly, Claim 53 distinguishes over the cited art.

In view of the preceding remarks, it should be evident that this application is in condition for allowance and should be passed to issue without delay. Should any further questions remain, the Examiner is invited to telephone applicants' attorney at the number listed below.

Respectfully submitted,

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